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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,795	12/06/2001	John P. Morseman	031676.0263	8799

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,795

Applicant(s)

MORSEMAN ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,7,9,13 and 14 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1) Claim 1, line 1, the spelling of "N-hydro~~xy~~succinimide" should be corrected.

2) Claims 1, 7 and 9-12 are allowed.

3) This application is in condition for allowance except for the following formal matters:

Claims 8 and 10-12, drawn to non-elected inventions, must be canceled.

4) Applicants' March 15, 2004 arguments with regard to the examiner's finding that claims 8 and 10-12 are directed to inventions which are independent or distinct from the invention originally claimed have been fully considered but they are not persuasive.

With regard to applicants' request for an additional formal restriction requirement for these claims, it is noted that paragraph **1)** of the final rejection is in compliance with the requirements of MPEP 821.03 which does not require an additional formal restriction requirement. The reasons for a holding of independence or distinctness is set forth in subparagraphs **a) – c)** of paragraph **1)** of the final rejection.

Although claim 10 has been amended to require the same "label" as that used in claim 1, the "bifunctional reagent" of claim 10 is of a different scope than the "N-hydroxysuccinimide (NHS)" of claim 1 (see applicants' statement in paragraph A. of page 5 of the March 15, 2004 response).

Contrary to applicants' assertion (March 15, 2004 Remarks, page 6, first full paragraph), the subject matter of claim 8 is not considered to be of the same scope as original claim 5. Original claim 5 required a specific limited combination of "hydrating label and activating reagent" (step c.) followed by "removing the activating agent" whereby the target is conjugated to the label (step d.). Claim 8, on the other hand, requires a different "step for releasing sequestration of said derivatized label and said means to permit reaction" (step iii). These limitations of claims 5 and 8 are clearly not of the same scope; an additional question for consideration would be whether or not the broad "step for" of claim 8, step iii. finds adequate enabling support in the specification.

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5) Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

6) An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

April 06, 2004



Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641